

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of: Schaller, Heinz, et al.

Serial No.: 09/383,978

Filed: August 26, 1999

For: *METHODS AND COMPOSITIONS FOR
EXPRESSING HETEROLOGOUS GENES IN
HEPATOCYTES USING HEPADNAVIRAL
VECTORS*

Attorney Docket No.: BBI-102CP

Group Art Unit: 1632

Examiner:

Assistant Commissioner for Patents
Washington, D.C. 20231

Certificate of First Class Mailing (37 CFR §1.8(a))

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3-28-00

Date of Signature and of Mail Deposit

By:

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Attorney for Applicants

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Dear Sir:

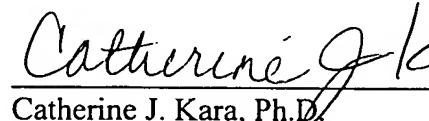
Applicants and their attorney have become aware of the following publications and information, cited in an International Search Report mailed February 15, 2000 during the prosecution of PCT/US99/19452 which corresponds to the above referenced application. In accordance with 37 CFR §1.97(b)(3), Applicants hereby submit these publications for the Examiner's consideration. These publications are cited on the enclosed PTO Form 1449, and a copy of the Report and each publication cited thereon are enclosed as well.

This statement is not to be interpreted as a representation that the cited publications are material, that an exhaustive search has been conducted, or that no other relevant information exists. Nor shall the citation of any publication herein be construed *per se* as a representation that such publication is prior art. Moreover, the Applicants understand that the Examiner will make an independent evaluation of the cited publications.

The undersigned hereby certifies that each item contained in this Supplemental Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this statement.

No additional costs are believed to be due in connection with the filing of this Supplemental Information Disclosure Statement. However, please charge any necessary fees in connection with the enclosed statement to our Deposit Order Account No. 12-0080.

Respectfully submitted,
LAHIVE & COCKFIELD, LLP



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Date: March 28, 2000

GAD/EAH/CJK/JLE/mlh
Enclosures

APPLICANT FACSIMILE OF FORM PTO-1449 REV 7-80		U S DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTY DOCKET NO BBI-102CP	SERIAL NO. 09/383,978
LIST OF PUBLICATIONS CITED BY APPLICANT (Use several sheets if necessary)		APPLICANT Schaller, Heinz et al.		
		FILING DATE August 26, 1999	GROUP 1632	

U.S. PATENT DOCUMENTS

FOREIGN PATENT DOCUMENTS

FOREIGN PATENT DOCUMENTS							
		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION
	B2	WO 98/09524	03/98	PCT			YES NO

OTHERS (including Author, Title, Date, Pertinent Pages, Etc.)

Examiner _____ Date Considered _____

***EXAMINER:** Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

APPLICANT FACSIMILE OF FORM PTO-1449		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTY DOCKET NO	SERIAL NO.
REV 7-80			BBI-102CP	09/383,978
LIST OF PUBLICATIONS CITED BY APPLICANT (Use several sheets if necessary)		APPLICANT	Schaller, Heinz et al.	
		FILING DATE	August 26, 1999	
		GROUP	1632	



U.S. PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
B1	5,981,274	11/99	Tyrrell et al.	435	320.1	

FOREIGN PATENT DOCUMENTS

FOREIGN PATENT DOCUMENTS							
		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION
							YES NO
<i>Entd</i>	B2	WO 98/09524	03/98	PCT			

OTHERS (including Author, Title, Date, Pertinent Pages, Etc.)

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LIST OF PUBLICATIONS CITED BY APPLICANT (Use several sheets if necessary)		APPLICANT		FILING DATE August 26, 1999	
		Schaller, Heinz et al.		GROUP 1632	

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES NO
<i>SMY</i>	A1	WO 90/02176	03/90	PCT			
<i>SMY</i>	A2	EP 421 635	04/91	EP			
<i>SMY</i>	A3	WO 95/06745	03/95	PCT			Abstr.
<i>SMY</i>	A4	WO 96/35797	11/96	PCT			yes
<i>SMY</i>	A5	WO 98/11916	03/98	PCT			

OTHERS (including Author, Title, Date, Pertinent Pages, Etc.)

<i>SMY</i>	A6	Chaisomchit, S. et al., "Development of replicative and nonreplicative hepatitis B virus vectors," <i>Gene Ther.</i> 4:1330-1340 (1997)
<i>SMY</i>	A7	Chiang, P.W., "Characterizing cis elements which are essential for the HBV replication," (1992) Thesis, University of Heidelberg
<i>SMY</i>	A8	Horwich, A.L. et al., "Synthesis of hepadnavirus particles that contain replication-defective duck hepatitis B virus genomes in cultured HuH7 cells," <i>J. Virol.</i> 64:642-650 (1990)
<i>SMY</i>	A9	Horwich, A.L. et al., "Inherited hepatic enzyme defects as candidates for liver-directed gene therapy," <i>Curr. Topics in Microbiology and Immunology</i> 168:185-201 (1991)
<i>SMY</i>	A10	Löser, Peter et al., "Evaluation of HBV Promoters for Use in Hepatic Gene Therapy," <i>Biol. Chem. Hoppe-Seyler</i> 377:187-193 (1996)
<i>SMY</i>	A11	Summers, Jesse et al., "Hepadnavirus Envelope Proteins Regulate Covalently Closed Circular DNA Amplification," <i>J. Virology</i> 64(6):2819-2824 (1990)
<i>SMY</i>	A12	Tuttleman et al., "In vitro experimental infection of primary duck hepatocyte cultures with duck hepatitis B virus," <i>J. Virol.</i> 58(1):17-25 (1986)

Examiner

<i>SMY</i>	Date Considered <i>5/18/00</i>
*EXAMINER/	Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.